

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed December 17, 2009. Claims 36, 38-49, and 73-78 were pending and rejected in view of cited art. Claims 36, 73, and 76 are amended. Claims 36, 38-49, and 73-78 remain pending in view of the above amendments of which claims 36, 73 and 76 are independent.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

The Office Action rejected claims 76-78 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Independent claim 76 has been amended. In view of the amendment, Applicant respectfully requests withdrawal of the rejection under Section 112.

### **C. PRIOR ART REJECTIONS**

#### **I. REJECTION UNDER 35 U.S.C. § 103**

The Office Action rejected claims 36, 38-40, 44 and 48 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Reissue Patent No. RE36,974 (*Bonutti*) in view of U.S. Patent No. 5,810,884 (*Kim*). Claims 41-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bonutti* in view of *Kim* as applied to claim 36, and further in view of U.S. patent No. 5,411,520 (*Nash*). Claims 45-47 and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bonutti* in view of *Kim* as applied to claim 36, and further in view of U.S. patent No. 6,506,197 (*Rollero*). Claims 73-78 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bonutti* in view of U.S. Patent No. 5,814,073 (*Bonutti* 2). Applicant

respectfully traverses because Applicant respectfully submits that the independent claims 36, 73, and 76 as presented for reconsideration are not anticipated nor made obvious by *Bonutti* either singly or in combination with any other reference of record.<sup>1</sup>

*Bonutti* discloses a suture anchor that includes, as illustrated in FIG. 1, "a cylindrical member with a tubular wall 12 extending about a longitudinal axis 14 of the anchor. The wall 12 has a cylindrical outer surface 16 and a cylindrical inner surface 18. The inner surface 18 of the anchor 10 defines a cylindrical central channel 20 extending longitudinally through the anchor 10" and which receives a suture (col. 4, ll. 8-13). In another configuration, and as illustrated in FIG. 20, "[a]n anchor 180 . . . is similar to the anchor 10 . . . but has four side openings through which a suture 82 enters and exits the anchor 180" (col. 7, ll. 32-34). *Bonutti*, however, does not describe the anchor being a bar that is "a solid piece of material except for a first bore extending laterally through the central region and generally perpendicular to the longitudinal axis, as recited in part, by claims 36, 73 and 73." Rather, the anchors of *Bonutti* include "cylindrical central channel 20 extending longitudinally through the anchor 10" or the unnumbered channel illustrated in FIG. 20. Even though the anchor 180 includes "four side openings through which a suture 82 enters and exits the anchor 180", anchor 180 is still not "a solid piece of material except for a first bore extending laterally through the central region and generally perpendicular to the longitudinal axis" because it includes a longitudinal "cylindrical central channel" that extends from the proximal end to the distal end.

*Bonutti* also describes

"[T]here are several features of the anchors of the present invention which contribute to their ease of use, especially in removal. They do not anchor themselves by digging into tissue as does a screw or an anchor with a pointed end. Instead, they rely on not being able to fit back through the hole they went in. Because they do not have axially inwardly extending slots or other non-uniform configurations at their ends, they can be turned within the cancellous bone to a vertical position (parallel to and aligned with the insertion opening) and thus made removable simply by pulling on the appropriate suture end. The non-oblique ends of the anchors, i.e., 90° end faces or curved or tapered end faces, do not bite into the bone and thus do not inhibit removability; rather, they allow easy rocking for change of orientation between insertion/removal and anchoring. The lack of knots avoids stress risers in the suture. There are no slots in the anchor to cut the suture."

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<sup>1</sup> Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

(col. 6, ln. 64-col. 7, ln. 13). *Bonutti* teaches away from anchors that include "non-uniform configurations" at proximal and/or distal ends of an anchor or other structures that could "inhibit removability." With respect to independent claims 73 and 76, which recite, in part, "an eyelet spaced apart from the first bore and extending from the proximal end", the "eyelet . . . extending from the proximal end" appears to create a "non-uniform configuration" to the anchor and so are contrary to the teaching of *Bonutti*. Thus, *Bonutti* neither teaches nor suggests, and can be considered as teaching away from the inventions claimed in independent claims 73 and 76.

With respect to *Kim*, the Office Action alleges that *Kim* discloses "a sharpened tip (48) on the distal end of a delivery device used to deliver a suture retaining element" (Office Action, p. 3). In a few configurations, *Kim* teaches the use of one or "two steering cables [which] remain rotatably attached to the buttressing support member" rather than the cylindrical-shaped plug closure or membrane/plate anchor closure (col. 27, ll. 21-23; see FIGS. 2A-3B.) *Kim* teaches away from the retractable nature of the filament of the claimed invention in stating that "the proximal ends [of the steering cables] are desirably joined to the skin as sutures for permanent and effective sealing of the puncture site" (col. 28, ll. 65-67 (emphasis added)). Consequently, the steering cable(s) are fixed at one end, so are not "a filament having a first free end and a second free end," as recited, in part, by independent claims 36, 73, and 76.

As illustrated in FIG. 9A, and as alleged described in the Office Action, "Kim further teaches using an eyelet and bore on the same bar (fig. 9a) so that a filament (14) may be threaded through both for additional control over the bar" (Office Action, p. 5). As described in *Kim*, "the anchor closure 100 has been threaded via the thru hole 103 and the attachment collar 104 onto the length of the extended steering cable 14" which is "held by the physician at one end and remains rotatably attached to the deployed and aligned buttressing support member" that was previously positioned against the posterior vascular wall (col. 24, ll. 35-38 and 65-67; see also col. 25, ll. 1-3). Attached to the attachment collar 104 is another anchor line (108) for additional control (see: col. 24, ll. 42-46). Neither the extended steering cable nor the anchor line 108 appears to be removed from the closure guiding stabilizer or the anchor closure 100. And consequently, neither is "a filament having a first free end and a second free end," as recited, in part, by independent claims 36, 73, and 76. Thus, even assuming *arguendo* that *Kim* were properly combinable with *Bonutti*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Bonutti* and *Kim*.

Accordingly, for at least the reasons noted, independent claims 36, 73, and 76, and the claims depending therefrom<sup>2</sup> are neither anticipated nor made obvious by *Bonutti*, either singly or in combination with any other prior art of record<sup>3</sup>, and thus reconsideration and withdrawal of the rejection is respectfully requested.

**D. CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

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<sup>2</sup> Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims.

<sup>3</sup> *Nash*, *Rollero*, and *Bonutti 2* were cited as secondary references. *Nash* was cited for the proposition that it discloses "a tensioning device in devices used to facilitate the sealing of a puncture" (Office Action, p. 4). *Rollero* was cited for the proposition that it discloses "a plurality of attachment points, such as holes, in a bar such that a filament can be securely attached to the bar," and *Bonutti 2* was cited as disclosing "use [of] an inserter with a sharpened tip at its distal end that is disposed upon a peripheral longitudinal side of the delivery sheath" (Office Action, p. 6). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Bonutti* or *Kim*. Thus, even assuming *arguendo* that any of the references to *Nash*, *Rollero*, and *Bonutti 2* are properly combinable with *Bonutti* or *Kim*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Bonutti* or *Kim*.

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